the United States and the Virgin Islands. The Network provides the HBCU's and Predominantly Black colleges and universities with programming, orientation, and satellite technology training sessions for faculty, staff, and students on satellite technology, program development and productions, and the integration of telecommunications into the curriculum. BCSN assists the member institutions: (1) in securing funding for productions to be broadcast to other campuses; and (2) with productions and uplinking of line programs from the colleges and universities.

BCSN provides in-service workshops for the colleges and universities as well as technical assistance in telecommunications to the faculty, administration, and students. There is no other telecommunications group with a comparable record and experience, minority or otherwise. The BCSN Board consists of 18 presidents of the member universities. The Network staff has over 100 years of combined experience and service to HBCU's.

Executive Order 12372 Review

The application is not subject to review as governed by Executive Order 12372, entitled ''Intergovernmental Review of Federal Programs.''

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.283.

Where To Obtain Additional Information

If you are interested in obtaining additional information regarding this project, please refer to Announcement 504 and contact Van Malone, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 320, Mailstop E–15, Atlanta, GA 30305, telephone (404) 842–6872.

A copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) referenced in the ''Summary'' may be obtained through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: June 2, 1995.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

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BILLING CODE 4163–18–P

[Announcement 548]

Fellowship Program in Violence Prevention for Minority Medical Students

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 funds for a cooperative agreement for a Fellowship Program in Violence Prevention for Minority Medical Students.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2000,'' a PHS-led national activity to reduce morbidity and mortality and to improve the quality of life. This announcement is related to the priority area of Violent and Abusive Behavior. (For ordering a copy of ''Healthy People 2000,'' see the section ''Where to Obtain Addition Information.'')

Authority

This program announcement is authorized under sections 391(a) and 393(a), of the Public Health Service Act (42 U.S.C. 280b(a), and 280b-2(a)), as amended.

Smoke-Free Workplace

PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Public law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Applications may be submitted by public and private, nonprofit and for-profit organizations, and governments and their agencies. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, State and local governments or their bona fide agents, federally recognized Indian tribal governments, Indian tribes or Indian tribal organizations are eligible to apply.

Availability of Funds

Approximately $50,000 is available in FY 1995 to fund one award. It is expected that the award will begin on or about September 30, 1995, and will be made for a 12-month budget period with a project period of 1 year.

Purpose

The purpose of this cooperative agreement is to provide minority medical students with training in violence prevention and epidemiologic research. Specifically, this award is intended to:

A. Develop and strengthen minority physicians leadership in violence prevention;

B. Provide education and research opportunities in violence prevention for minority medical students;

C. Provide a model for future violence prevention training programs at the undergraduate medical school level and;

D. Provide 8–12 week fellowships for four fellows, in rotation, to participate in epidemiologic research on violence and in violence prevention projects.

Program Requirements

Applicants must:

1. Demonstrate a 5-year history of developing and managing fellowship assistance and/or specialized training for minority medical students;

2. Demonstrate that faculty/staff committed to this project have experience supervising medical fellows and medical fellowship programs and;

3. Demonstrate experience in providing and managing fellowship programs which places no fewer than 30 fellows in a one year period, and which has placed no fewer than 250 fellows over the life of the program.

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under A. (Recipient Activities), and CDC will be responsible for the activities listed under B. (CDC Activities).

A. Recipient Activities:

Provide two fellows to participate in an 8–12 week program for each of two periods of performance, one in the fall of 1995, and the other in the winter of 1996, who will:

1. Review existing literature and data on violence prevention efforts and organize the information into text and table for a report;

2. Evaluate violence prevention strategies;

3. Analyze data and prepare written manuscripts for publication;

4. Observe technical assistance to local violence prevention projects; and

5. Make clear, concise presentations of projects completed during the fellowship period.

Fellows should be:

a. Second or third year medical students;

b. Able to organize and analyze data;

c. Interested in pursing a career in public health research, practice, or teaching.

B. CDC Activities:

1. Coordinate and facilitate orientation on CDC Division activities;

2. Provide related background and reading materials;

3. Coordinate site visits to funded projects and;

4. Coordinate and assign project activities.

Review and Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria (maximum 100 total points):

A. Background and Need (20%)

The extent to which the applicant presents data justifying need for the program in terms of magnitude of the related injury problem and the need for minority medical students' training in violence prevention. The extent to which a description of current and previous related experiences: (a) is inclusive in terms of fellowship activities and success, evaluation capability and coordination activities, and (b) demonstrates capacity to conduct the program.

B. Goals and Objectives (15%)

The extent to which the applicant has included goals which are relevant to the purpose of the proposal and feasible to be accomplished during the project period, and the extent to which these are specific, and measurable. The extent to which the applicant has included objectives which are feasible to be accomplished during the budget period, and which address all activities necessary to accomplish the purpose of the proposal. The extent to which the objectives are specific, time-phased, and measurable.

C. Methods (35%)

The extent to which the applicant provides a detailed description of proposed activities which are likely to achieve each objective and overall program goals and which includes designation of responsibility for each action undertaken. The extent to which the applicant provides a reasonable and complete schedule for implementing all activities. The extent to which roles of each Fellow and CDC are described, and coordination and supervision of Fellows in proposed activities is delineated. The extent to which documentation of program organizational location is clear. The extent to which position descriptions, CV's and lines of command are appropriate to accomplishment of program goals and objectives. The extent to which concurrence with the applicant's plans by all other involved parties is specific and documented.

D. Evaluation (30%)

The extent to which the proposed evaluation system is detailed and will document program process, effectiveness, impact, and outcome. The extent to which the applicant demonstrates potential data sources for evaluation purposes, and documents staff availability, expertise, and capacity to perform the evaluation. The extent to which a feasible plan for reporting evaluation results and using evaluation information for programmatic decisions is included.

E. Budget and Justification (Not Scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with stated objectives and planned program activities.

Executive Order 12372 Review

This program is not subject to the Executive Order 12372 review.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.136.

Other Requirements

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and are funded by the cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161–1 (OMB Number 0937-0189) must be submitted to Henry S. Cassell, III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305, on or before July 31, 1995.

1. Deadlines: Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date; or

b. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. Late Applications:

Applications which do not meet the criteria in 1.a. or 1.b. above are considered late. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked to leave your name, address and phone number and will need to refer to Announcement 548. You will receive a complete program description, information on application procedures, and application forms.

If you have any questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Adrienne Brown, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease

Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305, telephone (404) 842–6630. Programmatic technical assistance may be obtained from Timothy Thornton, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop K–60, Atlanta, GA 30333, telephone (404) 488–4389.

Please refer to Announcement 548 when requesting information and submitting an application.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) referenced in the ''Introduction'' through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: June 1, 1995.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

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Food and Drug Administration

[Docket Nos. 95P–0061, 95S–0117, 95S–0126, and 95S–0135]

Patent Term Extensions Under the Uruguay Round Agreements Act and Their Effects on Marketing Applications for Human and Animal Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of its response to a citizen petition from Glaxo Pharmaceuticals, Inc. (Glaxo). The petition requested that the agency announce how the Uruguay Round Agreements Act (URAA) will affect the patent information submission and patent certification requirements for applications to market drug products under the Federal Food, Drug, and Cosmetic Act (the act). FDA responded to the petition on May 25, 1995. The response provides applicants with current information on how the URAA will affect patent term extension requirements for applications to market human and animal drugs.

DATES: Amended patent information, reflecting any extended patent terms under the URAA, should be submitted to FDA before July 8, 1995, but no earlier than June 8, 1995.

ADDRESSES: Copies of the citizen petition (95P–0061/CP1), comments submitted to FDA regarding the citizen petition, and FDA's response to the citizen petition may be obtained from the Freedom of Information Staff (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857. Copies are also available for public examination at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION: On December 8, 1994, the URRA (Pub. L. 103–465) was signed into law. The URAA made amendments to Title 35 of the United States Code. These amendments relate to patent terms for existing and future patents, and they will become effective on June 8, 1995. Certain provisions of the URAA patent amendments will change the terms of some existing patents from 17 years from the date of the granting of the patent to 20 years from the filing of the patent application.

On February 16, 1995, the Patent and Trademark Office (PTO) held a public hearing on the patent provisions amended by the URAA. The PTO devoted a portion of the hearing to addressing several issues pertaining to the effect of these changes in patent law on FDA's enforcement of the act. (See the **Federal Register** notice of January 17, 1995 (60 FR 3398).) Oral testimony was given at the hearing and written submissions were made to PTO and FDA. Glaxo submitted its citizen petition to FDA on March 7, 1995. The petition requested that the agency announce the effect the URAA will have on the patent information submission and patent certification requirements for applicants to market drug products under the act. FDA has received a number of responses to Glaxo's citizen petition from generic and innovator drug manufacturers. Glaxo submitted an additional comment on the responses dated April 13, 1995. These documents are included in Docket No. 95P–0061. These oral and written submissions were considered by FDA in developing its response to the petition.

A brief summary of FDA's position on patent term extensions under the URAA is set out below in this document. A fuller exposition of the agency's position may be found in the response to Glaxo's petition.

I. Submission of Patent Information

FDA has determined that if the patent term expiration date for a listed human or animal drug product is extended by the URAA, the new drug application (NDA) or new animal drug application (NADA) holder must submit information on the new patent term expiration date to FDA after June 8, 1995, but before July 8, 1995. NDA holders who have already submitted information indicating that listed patents will be extended by the URAA should resubmit this information on or after June 8, 1995.

Two copies of amended patent information pertaining to human drug products regulated under section 505 of the act (21 U.S.C. 355) by the Center for Drug Evaluation and Research (CDER) should be submitted to the assigned reviewing division. The submission should bear the pertinent NDA number. Two copies of amended patent information pertaining to human drug products regulated under section 505 of the act by the Center for Biologics Evaluation and Research (CBER) should be sent to the Document Control Center, Center for Biologics Evaluation and Research (HFM–99), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

To expedite the availability to the public of the updated patent information, a third copy of the amended patent information pertaining to human drug products regulated under section 505 of the act by either CDER or CBER should be sent to the Drug Information Services Branch, Center for Drug Evaluation and Research, Food and Drug Administration (HFD–84), 5600 Fishers Lane, Rockville, MD 20857.

Amended patent information pertaining to animal drug products should be sent to the Document Control Unit, Center for Veterinary Medicine (HFV–199), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

II. Public Availability of Updated Patent Information

Updated information related to patents on human drug products regulated by CDER will be placed on public display in the Dockets Management Branch (address above) under Docket No. 95S–0117, after June 8, 1995. Updated information related to patents on human drug products regulated by CBER will be placed on